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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,780	08/18/2000	Jacques Dumas	BAYERSC1	7350

23599 7590 05/05/2005

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EXAMINER	
OWENS, AMELIA A	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/640,780	DUMAS ET AL.	
	Examiner	Art Unit	
	Amelia A. Owens	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,11-13,15,16,37,41-43,46 and 80-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,11-13,15,16,37,41-43,46 and 80-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,9,11,12,13,15,16,37,41-43,46,80-87 are pending. No drawings were filed with the application. Foreign priority was not claimed.

Claim Rejections - 35 USC § 112

Claims 1,9,11,12,13,15,16,37,41-43,46,80-87 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' comments have been considered and the rejection will be maintained. The issue still remains that not all cancers respond equally to the effects on the ras/raf pathway. This means that some cancers do not respond at all to the ras/raf pathway. Moreover, that is the basis for an enablement rejection. While the ras/raf pathway is correlated to many cancers, some highly, some intermediately, it is not correlated to ALL cancers which is what applicants are claiming and have not sufficiently enabled. The state of the art is that cancer treatment remains highly unpredictable, ergo the art recognizes that the ras/raf pathway is not effective in treating all forms of cancer. See Kolch et al , 'The role of Raf kinases in malignant transformation', at page 10, column 2 lines 18-44 whch states that the pathway is hyperactive in only about 30% of all human cancer.

While the case law is clear, applicants' have yet to establish one operative embodiment. The art recognizes that compounds that are active via the ras/raf pathway ultimately have some success in treating various forms of cancer. However, applicant has not demonstrated that the claimed compounds are active via the ras/raf pathway. This is why the compounds were

included in the rejection. It has yet to be established that the claimed compounds have a viable utility. The language at page 2 describing the use of the claimed compounds is prophetic at best. The language merely describes applicants' intent for the compound. Applicant is invited to come in with a declaration utilizing the claimed compounds via the claimed pathway showing positive cancer treatment.

The test data at pages 112-114 is noted. In the first test, no cells are used. Further it is not clear that either the first or second assay correlate to any form of cancer treatment. There is no evidence of functional treatment, i.e. no correlation to treatment in humans. Again, the art recognizes that compounds active via the ras/raf pathway are effective in treating various forms of cancer. Where is the evidence that the same is true of applicants' compounds? Specific experimental data demonstrating the claimed compounds effective on cancerous cell growth via the ras/raf pathway is not disclosed.

Even though the level of skill in the cancer therapy art is very high, the quantity of experimentation would be undue when faced with a lack of direction and guidance as in the instant case. Arguably, given proper direction and guidance one of ordinary skill in the art in view of what is known in the art would know how to practice the claimed invention. However, applicants have not shown the claimed compounds, not even a single compound according to the invention, effective via the ras/raf pathway. Given the unpredictability of cancer treatment, why would one of ordinary skill in the art use the claimed compounds to treat ANY form of cancer via the ras/raf pathway? Never mind ALL forms of cancer as are instantly claimed. Where is the direction and guidance? Again, specific experimental data for the claimed compounds on

cancerous cell growth is not disclosed. Applicants' assertions either that the compounds would be effective *or* that the compounds are effective are not enough.

This means the skilled artisan would have to ascertain if indeed the claimed compounds are active via the ras/raf pathway and then further determine which cancers the compounds are active against. This would seem to be undue experimentation. For the above reasons, the claimed invention is not seen to be enabled.

Claims 1,9,11-13,16,80,81,87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification at page 2 at lines 11-14 state the compounds are effective against 'solid tumors' and then lists ---myeloid leukemia---. Leukemia is not a solid cancer. See Merck Manual, sec.11, ch. 138 attached, which states leukemia are neoplasms of blood forming tissue.

The rejection under 35 USC 112, second paragraph has been dropped. Applicants' comments are persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMELIA AVERILL OWENS
PRIMARY EXAMINER